

We claim:

1. A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for one or more analytes comprising:

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- i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra characterized as having a negative slope for a continuous spectral segment from about 5 nm to about 200 nm in length said spectral segment including a principal calibration wavelength for said one or more analytes;
 - ii) calculating one or more concentration values from said measurement using said one or more calibration algorithms;
 - iii) comparing said one or more concentration values with an assigned value given to said quality control material for each of said one or more analytes; and
 - iv) determining if there is a violation of a pre-established quality control rule, thereby monitoring said one or more calibration algorithms of said apparatus

2. The method of claim 1, wherein said one or more analytes is one or more analytes in a biological fluid selected from the group consisting of serum, plasma, urine, synovial fluid and cerebrospinal fluid.

3. The method of claim 2, wherein said one or more analytes is bilirubin, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

4. The method of claim 2, wherein said one or more analytes is an indicator of hemolysis, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

5. The method of claim 2, wherein said one or more analytes is a hemoglobin-based blood substitute, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

6. The method of claim 2, wherein said one or more analytes is met-hemoglobin, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

7. The method of claim 2, wherein said one or more analytes is methylene blue, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

8. The method of claim 2, wherein said one or more analytes is biliverdin, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

9. A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for a perfluorocarbon-like blood substitute, turbidity, or a combination thereof, wherein said turbidity is measured in concentration units of a lipid emulsion, comprising:

i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra within the range from about 700 nm to about 1100 nm;

ii) calculating one or more concentration values from said measurement using said one or more calibration algorithms;

iii) comparing said one or more concentration values with an assigned value given to said quality control material for each of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof; and

iv) determining if there is a violation of a pre-established quality control rule, thereby monitoring said one or more calibration algorithms of said apparatus

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10. A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for a perfluorocarbon-like blood substitute, turbidity, or a combination thereof wherein said turbidity is measured in concentration units of a lipid emulsion, comprising:

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- i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra characterized as having a negative slope for a continuous spectral segment from about 5nm to about 400nm within the range of the absorbance spectra from about 700 nm to about 1100 nm;
 - ii) calculating one or more concentration values from said measurement using said one or more calibration algorithms;
 - iii) comparing said one or more concentration values with an assigned value given to said quality control material for of said one or more of a perfluorocarbon-like blood substitute, turbidity, or a combination thereof, wherein said turbidity is measured in concentration units of a lipid emulsion; and
 - iv) determining if there is a violation of a pre-established quality control rule, thereby monitoring said one or more calibration algorithms of said apparatus

11. The method of claim 1, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

12. The method of claim 9, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

13. The method of claim 10, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

14. The method of claim 11, wherein said absorbance spectra of said one or more substances is altered by adding a spectral modifier.

15. The method or claim 14, wherein said modifier causes a non-additive spectral shift in said absorbance spectra.

16. The method of claim 15, wherein said modifier is selected from the group consisting of a polymer, a protein, amaranth, and a combination thereof.

17. The method of claim 16, wherein said polymer is selected from the group consisting of PVP and PEG.

18. A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

- i) monitoring calibration of said apparatus as defined in claim 1;
- ii) establishing that there is no violation of a pre-established quality control rule;
- iii) measuring absorbance values of said sample;
- iv) calculating an order derivative of absorbance of said sample; and
- v) calculating a concentration of said one or more analytes in said sample, by applying said at least one primary calibration algorithm to said order derivative of absorbance value.

19. A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

- i) monitoring calibration of said apparatus as defined in claim 9;
- ii) establishing that there is no violation of a pre-established quality control rule;
- iii) measuring absorbance values of said sample;
- iv) calculating an order derivative of absorbance of said sample; and
- v) calculating a concentration of one or more of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof, in terms of concentration of a lipid emulsion in said sample, by applying said primary calibration algorithm to said order derivative of absorbance value.

20. A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

- i) monitoring calibration of said apparatus as defined in claim 10;
- ii) establishing that there is no violation of a pre-established quality control rule;
- iii) measuring absorbance values of said sample;
- iv) calculating an order derivative of absorbance of said sample; and
- v) calculating a concentration of one or more of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof, in terms of concentration of a lipid emulsion in said sample, by applying said primary calibration algorithm to said order derivative of absorbance value.

21. The method of claim 18, wherein said one or more analytes is one or more analytes in a biological fluid selected from the group consisting of whole blood, serum, plasma, urine, synovial fluid and cerebrospinal fluid.

22. The method of claim 21, wherein said one or more analytes is bilirubin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

23. The method of claim 21, wherein said one or more analytes is an indicator of hemolysis, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

24. The method of claim 21, wherein said one or more analytes is a hemoglobin-based blood substitute, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

25. The method of claim 21, wherein said one or more analytes is met-hemoglobin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

26. The method of claim 21, wherein said one or more analytes is methylene blue, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

27. The method claim 21, wherein said one or more analytes is biliverdin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

28. The method of claim 18, wherein said quality control material comprises one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

29. The method of claim 28, wherein said absorbance spectra of said one or more substances is altered by adding a spectral modifier.

30. The method of claim 29, wherein said modifier causes a non-additive spectral shift in said absorbance spectra.

31. The method of claim 30, wherein said modifier is selected from the group consisting of a polymer, a protein, and amaranth.

32. The method of claim 31, wherein said polymer is selected from the group consisting of PVP and PEG.

33. A method for selecting one or more substances as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus comprising:

- i) identifying a principal calibration wavelength for each of one or more analytes;
- ii) screening absorption spectra of said one or more substances; and
- iii) selecting one or more of said substances exhibiting a negative slope of said absorbance spectra, for a continuous spectral segment from about 5 nm to about 200 nm in length, said spectral segment including said principal calibration wavelength.

34. The method of claim 33, wherein said one or more analytes is one or more analytes in a biological fluid selected from the group consisting of serum, plasma, urine, synovial fluid and cerebrospinal fluid.

35. The method of claim 34, wherein said one or more analytes is bilirubin, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

36. The method of claim 34, wherein said one or more analytes is an indicator of hemolysis, and in said step of selecting (step iii), said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

37. The method of claim 34, wherein said one or more analytes is a hemoglobin-based blood substitute, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

38. The method of claim 34, wherein said one or more analytes is met-hemoglobin, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

39. The method of claim 34, wherein said one or more analytes is methylene blue, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

40. The method of claim 34, wherein said one or more analytes is biliverdin, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

41. The method of claim 33, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

42. The method of claim 33 wherein in said step of identifying (step i)), said principal calibration wavelength of said analyte, and in said step of screening (step ii))

said absorption spectra of said one or more substances, are obtained on said spectrophotometric apparatus having one or more primary calibration algorithms.

43. A method for selecting one or more substances as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus for one or more of a perfluorocarbon-like blood substitute and turbidity, wherein turbidity is measured in terms of concentration units of a lipid emulsion, comprising:

- i) identifying a principal calibration wavelength for each of one or more of said perfluorocarbon-like blood substitute and said turbidity;
- ii) screening absorption spectra of said one or more substances; and
- iii) selecting one or more of said substances exhibiting absorbance within the range from about 700 nm to about 1100 nm.

44. A method for selecting one or more substances as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus for one or more of a perfluorocarbon-like blood substitute and turbidity wherein turbidity is measured in terms of concentration units of a lipid emulsion, comprising:

- i) identifying a principal calibration wavelength for each of one or more of said perfluorocarbon-like blood substitute and said turbidity;
- ii) screening absorption spectra of said one or more substances; and
- iii) selecting one or more of said substances exhibiting absorbance spectra as having a negative slope for a continuous spectral segment from about 5nm to about 400nm within the range of wavelengths from about 700 nm to about 1100 nm.

45. A method of monitoring the calibration of a reagentless spectrophotometric apparatus comprising one or more calibration algorithms for one or more analytes in a sample, said method comprising:

- i) measuring absorbance of a quality control material with said reagentless spectrophotometric apparatus to obtain one or more measurements, said quality

control material comprising one or more substances that absorb electromagnetic radiation, whereby predicted values for said one or more analytes can be obtained;

ii) calculating one or more of said predicted values from said one or more measurements;

iii) comparing said one or more of said predicted values with one or more assigned values given to said quality control material for said one or more analytes; and

iv) determining if there is a violation of a pre-established quality control rule, thereby monitoring said calibration algorithms of said reagentless spectrophotometric apparatus.

46. The method of claim 45, wherein said measuring (step i)) can be performed in any transparent or translucent vessel.

47. The method of claim 45, wherein said sample is a biological fluid, non-biological fluid, semi-solid, or a soft solid.

48. The method of claim 47, wherein said sample is selected from the group consisting of whole blood, serum, plasma, synovial fluid, cerebrospinal fluid, urine, mucus, lymphatic fluid, semen, milk, cheese, cottage cheese, yogourt, ice cream, beverage and feces.

49. The method of claim 45, wherein said one or more calibration algorithms are developed using a statistical technique selected from the group consisting of simple linear regression, multiple linear regression, partial least squares and principal component analysis.

50. The method of claim 45, wherein said one or more wavelengths used in said one or more calibration algorithms is selected from the range from about 450nm to 3000nm.

51. The method of claim 45, wherein said one or more analytes are selected from the group consisting of a simulator of turbidity, a perfluorocarbon-like blood substitute, bilirubin, an indicator of hemolysis, a Hb-based blood substitute, methylene blue, met-Hb and biliverdin, and said sample is selected from the group consisting of whole blood, serum, plasma, urine, synovial fluid and cerebrospinal fluid.

52. A quality control material for mimicking two or more analytes comprising, one or more substances having a combined absorption spectrum exhibiting a negative slope for a continuous spectral segment from about 5 nm to 200 nm in length, in a portion of an absorption spectrum, including one or more principal calibration wavelengths, for said two or more analytes.

53. The quality control material of claim 52, wherein one of said two or more analytes is bilirubin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

54. The quality control material of claim 52, wherein one of said two or more analytes is an indicator of hemolysis, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

55. The quality control material of claim 52, wherein said two or more analytes are selected from the group consisting of whole blood, serum, plasma, synovial fluid, cerebrospinal fluid, urine, mucus, lymphatic fluid, semen and feces.

56. The quality control material of claim 52, wherein one of said two or more analytes is a hemoglobin-based blood substitute, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

57. The quality control material claim 52, wherein one of said two or more analytes is met-hemoglobin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

58. The quality control material claim 52, wherein one of said two or more analytes is methylene blue, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

59. The quality control material claim 52, wherein one of said two or more analytes is biliverdin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

60. The quality control material claim 52, wherein one of said two or more analytes is either a simulator of turbidity or a perfluorocarbon-like blood substitute, said quality control material further characterized as having an absorbance spectrum within the range of from about 700 nm to about 1100 nm.

61. The quality control material claim 52, wherein one of said two or more analytes is either a simulator of turbidity or a perfluorocarbon-like blood substitute, said absorption spectrum of said quality control material further characterized as having a negative slope for a continuous spectral segment from about 5nm to about 400nm within the range of from about 700 nm to about 1100 nm.

62. The quality control material of claim 52, further comprising one or more substances selected from the group consisting of a dye copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, a perfluorocarbon-like blood substitute, and a combination thereof.

63. The quality control material of claim 61, wherein an absorbance spectrum of said one or more substances is altered by adding a spectral modifier.

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64. The quality control material of claim 63, wherein said modifier causes a non-additive spectral shift in said absorbance spectra.

65. The quality control material of claim 64, wherein said modifier is selected from the group consisting of a polymer, a protein, and amaranth.

66. The quality control material of claim 65, wherein said polymer is selected from the group consisting of PVP and PEG.

67. A quality control material for use in a reagentless spectrophotometric apparatus, comprising one or more substances that mimic one or more analytes in serum, plasma, urine, synovial fluid or cerebrospinal fluid.

68. The quality control material of claim 67, wherein said one or more analytes is selected from the group consisting of a simulator of turbidity, a perfluorocarbon-like blood substitute, bilirubin, an indicator of hemolysis, a Hb-based blood substitute, methylene blue, met-Hb and biliverdin.

69. The quality control material of claim 68, wherein said one or more analyte is an indicator of hemolysis in serum or plasma, wherein said indicator of hemolysis is one of total Hb, oxy-Hb or "total Hb minus met-Hb", and wherein said quality control material is exposed to atmospheric conditions.

70. The quality control material of claim 69, wherein said one or more substances are selected from the group consisting of amaranth, acid fuchsin, basic fuchsin, ponceau S, chromotrope 2R, phenol red, crystal ponceau, methyl orange, a Hb-based blood substitute, total Hb, oxy-Hb, carboxy-Hb, cyanmet-Hb, a polymer, and a protein.

71. A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics an indicator of hemolysis, wherein said indicator of hemolysis is selected from the group consisting of oxy-Hb and "total Hb

minus met-Hb", and wherein said quality control material is exposed to atmospheric conditions.

72. The quality control material of claim 71, wherein said quality control material is not supplemented with bilirubin.

73. A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics an indicator of hemolysis, wherein said one or more substances are selected from the group consisting of total Hb, oxy-Hb, "total Hb minus met-Hb," cyanmet-Hb, amaranth, acid fuchsin, basic fuchsin, ponceau S, chromotrope 2R, phenol red, crystal ponceau, methyl orange, a Hb-based blood substitute, oxy-Hb, carboxy-Hb, cyanmet-Hb, a polymer, and a protein., and wherein said quality control material is exposed to atmospheric conditions.

74. The quality control material of claim 73, wherein said quality control material is not supplemented with bilirubin.

75. A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics an indicator of hemolysis, wherein said one or more substances are selected from the group consisting of total Hb, oxy-Hb, "total Hb minus met-Hb," cyanmet-Hb, acid fuchsin, basic fuchsin, ponceau S, chromotrope 2R, phenol red, crystal ponceau, methyl orange, a Hb-based blood substitute, oxy-Hb, carboxy-Hb, cyanmet-Hb, a polymer, and a protein.

76. The quality control material of claim 75, wherein said quality control material is not supplemented with bilirubin.

77. A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimic an indicator of hemolysis, wherein said indicator of hemolysis is selected from the group consisting of oxy-Hb and "total Hb minus met-Hb."

78. The quality control material of claim 77, wherein said quality control material is not supplemented with bilirubin.

79. A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics one or more of, biliverdin, bilirubin, methylene blue, met-Hb, a simulator of turbidity, a perfluorocarbon-like blood substitute, a Hb-based blood substitute.

80. A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics one or more of, an indicator of hemolysis, biliverdin, bilirubin, methylene blue, met-Hb, a simulator of turbidity, a perfluorocarbon-like blood substitute, a Hb-based blood substitute wherein said indicator of hemolysis is selected from the group consisting of oxy-Hb and "total Hb minus met-Hb".

81. The quality control material of claim 80, wherein said quality control material is not supplemented with bilirubin

82. A quality control material for use in a reagentless spectrophotometric apparatus, comprising, one or more substances that mimics an indicator of hemolysis, wherein said substance is selected from the group consisting of total-Hb and oxy-Hb, wherein said oxy-Hb accounts for about 95% of total Hb, or said total-Hb comprises about 95% oxy-Hb, and wherein said quality control material is exposed to atmospheric conditions.

83. The quality control material of claim 82, wherein said quality control material is not supplemented with bilirubin

84. A method for producing a corrected predicted value for an indicator of hemolysis in a sample, in the presence of met-Hb, said method comprising the steps of:

- i) developing a first primary calibration algorithm for one of a total Hb or an oxy-Hb, for predicting a first value for either said total Hb or said oxy-Hb in said sample;
- ii) deriving a second primary calibration algorithm for said met-Hb, for predicting a second value for said met-Hb in said sample; and
- iii) adding said predicted second value for said met-Hb to either said predicted first value for total Hb or said predicted first value for oxy-Hb, to a produce a said corrected predicted value for an indicator of hemolysis.

85. The method of claim 84, wherein said step of developing (step i)) and said step of deriving (step ii)), each comprises the steps of:

- a) collecting an absorbance measurement for each calibration sample in a primary calibration set, said calibration sample having known reference values for each analyte;
- b) calculating an order derivative of absorbance for each of said calibration sample; and
- c) creating a primary calibration algorithm for each of said indicator of hemolysis and said met-Hb using said derivative of absorbance, said known reference values, and a statistical technique.

86. The method of claim 85, wherein in said step of collecting (step a)), said reference values for either said total Hb or said oxy-Hb, are obtained from the measured amounts of said total Hb or said oxy-Hb, in the presence of one or more of oxy-Hb, deoxy-Hb, carboxy-Hb and met-Hb in said calibration samples.

87. The method of claim 86, wherein wherein said oxy-Hb accounts for about 95% of total Hb, or wherein said total-Hb comprises about 95% oxy-Hb

88. The method of claim 84, wherein said sample is one of serum, plasma, urine, synovial fluid or cerebrospinal fluid.

89. The method of claim 85, wherein in said step of creating (step c)), said statistical technique is selected from the group consisting of simple linear regression, multiple linear regression, partial least squares, and principal component analysis.

90. A method for flagging a predicted value for an indicator of hemolysis in a sample, in the presence of met-Hb, said method comprising the steps of:

- i) developing a first primary calibration algorithms for one of a total Hb or an oxy-Hb, for predicting a value for either said total Hb or said oxy-Hb in said sample;
- ii) deriving a second primary calibration algorithm for said met-Hb, for predicting a second value for said met-Hb in said sample;
- iii) determining if said predicted met-Hb value exceeds a pre-determined value; and
- iv) flagging said predicted value for said total Hb, said oxy-Hb or a combination thereof, when said predicted met-Hb value exceeds said pre-determined value.

91. The method of claim 90, wherein said step of developing (step i)) and said step of deriving (step ii)), each comprises the steps of:

- a) collecting an absorbance measurement for each calibration sample in a primary calibration set, said calibration sample having known reference values for each analyte;
- b) calculating an order derivative of absorbance for each of said calibration sample; and
- c) creating a primary calibration algorithm for each of said indicator of hemolysis and said met-Hb using said derivative of absorbance, said known reference values, and a statistical technique.

92. The method of claim 91, wherein in said step of collecting (step a)), said reference values for each of said total Hb or said oxy-Hb are obtained from the measured amounts

of said total Hb or said oxy-Hb, in the presence of one or more of oxy-Hb, deoxy-Hb, carboxy-Hb and met-Hb in said calibration samples.

93. The method of claim 92 wherein said oxy-Hb accounts for about 95% of total Hb, or wherein said total-Hb comprises about 95% oxy-Hb

94. The method of claim 90, wherein said sample is one of serum, plasma, urine, synovial fluid or cerebrospinal fluid.

95. The method of claim 91, wherein in said step of creating (step c)), said statistical technique is selected from the group consisting of simple linear regression, multiple linear regression, partial least squares, and principal component analysis.

96. The quality control material of claim 70, wherein said one or more substances is not supplemented with bilirubin.

97. The quality control material of claim 62, wherein said one or more substances is not supplemented with bilirubin.

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